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| 10/577,177 | 02/05/2007 | Alejandro Balazs | C1233,70001US01 | 4085 |
| 23628 7590 12/11/2008 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206 | | | | |
| EXAMINER | | | | |
| SGAGIAS, MAGDALENE K | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1632 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/577,177

Applicant(s)

BALAZS ET AL.

Examiner

MAGDALENE K. SGAGIAS

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) 13 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-12 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 25 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date 11/23/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

The previous restriction requirement mailed on 8/11/08 has been vacated and a new restriction requirement has been set forth below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) **1-12**, drawn to a method for obtaining a substantially pure population of hematopoietic stem cells, comprising: (a) contacting a biological sample comprising cells with an affinity agent which binds to endothelial protein C receptor (EPCR) under conditions appropriate for binding to occur, and (b) separating cells that bind to the affinity agent from cells that do not bind to the affinity agent, thereby producing a substantially pure population of hematopoietic stem cells..

Group II, claim(s) **13**, drawn to a method for treating a subject using hematopoietic stem cell transplantation, comprising implanting into the subject the substantially pure population of human hematopoietic stem cells of claims 5-12.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-II is contacting a biological sample comprising cells with an affinity agent which binds to endothelial protein C receptor (EPCR) under conditions appropriate for binding to occur, and separating cells that bind to the affinity agent from cells that do not bind to the affinity agent, thereby producing a substantially pure population of hematopoietic stem cells. **Wognum et al**, [Archives of Medical Research 34: 461-475, 2003,

(IDS)] teach CD201 (also known as endothelial protein C receptor [EPCR]) purified mouse EPCR cells were highly enriched for HSCs, indicating that EPCR/CD201 may be a useful marker for the detection and isolation of murine HSCs in future studies and expression of the human EPCR/CD201 gene has also been detected in gene profiling studies of primitive human hematopoietic cells, suggesting that it may be a useful marker for human HSC purification as well (p 464, 1st column, 1st paragraph). Therefore the instant technical feature of Groups I-II does not make a contribution over the prior art. Furthermore, the claimed methods of Groups I-II have distinct method steps, produce different products and/or results, which are not coextensive.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, this application contains:

1. Claim 3 and 8 generic to a plurality of disclosed patentably distinct species consisting of: column chromatography, fluorescence- activated cell sorting, magnetic bead separation and direct immune adherence.
2. Claim 4 and 9 generic to a plurality of disclosed patentably distinct species consisting of: bone marrow cells, embryonic yolk sac, fetal liver, fetal and adult spleen and blood.

Applicant is required under 35 USC 121 to elect **only one single species**, for each one of claims 3, 4, 8, and 9 corresponding to the elected group even though this requirement is traversed.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be

traversed (37 CFR 1.143) and (ii) **identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Patricia Granahan on 11/20/08 a provisional election was made without traverse to prosecute the invention of group I, claims 1-12. Applicants elected fluorescence-activated cell sorting for the species of claims 3 and 8. Applicants also elected bone marrow for the election of species for claims 4 and 9. Affirmation of this election must be made by applicant in replying to this Office action. Claim 13 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-13 are pending.

Claims 1-12 are under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Wognum et al**, [Archives of Medical Research 34: 461-475, 2003, (IDS)].

Wognum teaches contacting mouse bone marrow cells with the mouse EPCR/CD201 antibody for cell sorting of a population of EPCR+ hematopoietic stem cells (p 464, 1st column, 1st paragraph) (claims 1-9, 11-12). Wognum et al teaches that expression of the human EPCR/CD201 gene has been detected in gene profiling studies of primitive human hematopoietic cells (p 464, 1st column, 1st paragraph). Wognum suggests that it may be a useful marker for human HSC purification as well (p 464, 1st column, 1st paragraph). Therefore it would have been prima facie obvious for an ordinary of skill in the art to use human bone marrow cells for sorting EPCR+ human hematopoietic stem cells (claim 10).

Thus, the claimed invention as a whole, is clearly prima facie obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAGDALENE K. SGAGIAS whose telephone number is (571)272-3305. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the

status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632